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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,567	LEC ET AL.	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-51* is/are pending in the application.

4a) Of the above claim(s) *17-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35-37,39,41-43 and 48-51* is/are rejected.

7)☐ Claim(s) *34, 38, 40, 44-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

2. Claims 33, 35, 36, and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner (US 4981779).

Regarding claim 33, Wagner discloses a device for analyzing blood comprising a transducer element (elements 12a, 14a, 32, 32a, where the optical fiber applying the signal is a part of the transducer as a whole), a biologically active substance in communication with the transducer element that promotes interactions between the blood and the transducer element (element 20), a signal driver in communication with the transducer element that applies a signal to the transducer element (column 3, lines 25-26), where a value of the signal may be varied (the source may be turned on and turned off), an inlet port configured to direct blood to the transducer element (column 6, lines 63-66), and a signal processor in communication with the transducer element that measures a response of the blood to the signal (column 6, lines 35-41) and determines a characteristic of the blood as a function of the measured response (column 5 line 51 to column 6 line 5).

Regarding claim 35, Wagner further discloses the transducer element comprising an array of sensors (elements 12a, 14a).

Regarding claim 36, Wagner further discloses the biologically active substance facilitating determination of a characteristic of the blood (column 5, lines 15-26).

Regarding claim 41, Wagner further discloses the transducer element creating an effect having a depth of penetration into the blood of between 1 nanometer and 1 centimeter (since the device is configured to be inserted into a blood stream - column 6, lines 43-44 - the depth of penetration of the "effect" (light) cannot be more than a centimeter, based on the distance shown between the end of light fiber 12a and support 28 in figure 4).

Regarding claim 42, Wagner further discloses a catheter in communication with the transducer (element 27).

Regarding claim 43, Wagner further discloses the device being self-administered (column 7, lines 52-53).

Claim Rejections - 35 USC § 103

3. Claims 33, 35, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yim (US 5047627) in view of Maxwell (US 5048525).

Regarding claim 33, Yim discloses a device for analyzing blood comprising a transducer element (element 17, where the optical fiber applying the signal is part of the transducer as a whole - elements 17, 51', 53', 57', 59', 61', 65'), a biologically active substance in communication with the transducer element that promotes interactions between the blood and the transducer element (element 22), a signal driver in communication with the transducer element that applies a signal to the transducer element and varies a value of that signal (elements 51', 53'), a structure configured to direct blood to the transducer element (element 27), and a signal processor in

communication with the transducer element that measures a response of the blood to the signal and determines a characteristic of the blood as a function of the measured response (column 13, lines 45-54). Yim does not specifically disclose the structure configured to direct blood to the transducer element being a port. Maxwell teaches a similar blood analysis system comprising a port (element 63) configured to direct blood to a transducer element (elements 69, 71, 83), in order to control the exposure of the transducer element to blood. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Yim with a port configured to direct blood to the transducer element, as taught by Maxwell, in order to control the exposure of the element to blood.

Regarding claim 35, Yim further discloses the transducer element comprising an array of sensors (elements 17, 19).

Regarding claim 37, Yim further discloses varying the applied frequency (column 13, lines 9-54; wavelength is inversely proportional to frequency).

Regarding claim 39, Yim further discloses the different values being provided to the transducer sequentially (column 13, lines 19-21).

4. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner in view of Jina (US 6673622).

Wagner discloses all the elements of the claimed invention, as described above, except for the device comprising data storage, processing, and transmission of physiological characteristics, and providing information to a patient. Jina teaches a

blood characteristic analysis system comprising data storage, processing, and transmission, including storing blood data and providing information to a patient via a display (column 6 line 30 to column 7 line 23), in order to effectively analyze and use the gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Wagner with data storage, processing, transmission, and display of information, as taught by Jina, in order to effectively analyze and use the gathered data.

5. Claims 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner in view of Stiene (US 2004/0072357).

Wagner discloses all the elements of the claimed invention, as described above, except for the device comprising data storage, processing, and transmission, and wired and wireless communication. Stiene teaches a blood characteristic analysis system comprising data processing, storage, and transmission, including wired and wireless communication between the device, a patient, and a health center (paragraphs [0044], [0055]-[0066], [0078], [0115]), in order to facilitate analysis of gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Wagner with data processing, storage, and transmission, as well as wired and wireless communication, as taught by Stiene, in order to facilitate data analysis.

Allowable Subject Matter

6. Claims 34, 38, 40, and 44-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claim 34, including, *inter-alia*, a piezoelectric, electrostrictive, magnetostrictive, acoustooptic, and/or thermoacoustic sensor transducer element that interacts with blood in response to an applied varying signal value, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the inventions of claim 38, including, *inter-alia*, a device for analyzing blood comprising a signal driver applying a signal with a varying frequency between 1 KHz and 10 GHz to a transducer in communication with blood and a biologically active substance to determine a characteristic of the blood as a function of its response to the signal, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the inventions of claim 40, including, *inter-alia*, a device for analyzing blood comprising a signal driver applying a signal with varying frequency including resonant, antiresonant, harmonic, and/or antiharmonic frequencies of first and higher orders to a transducer in communication with blood and a biologically active substance to determine a characteristic of the blood as a function of its response to the signal, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claim 44, including, *inter-alia*, a blood analysis device comprising two acoustic sensors, one for analyzing the blood and the other for comparing the blood to a reference fluid, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claim 45, including, *inter-alia*, a blood analysis device coated with collagen that applies a varying frequency to determine platelet adhesion at a higher frequency and coagulation at a lower frequency, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claim 46, including, *inter-alia*, a blood analysis device coated with tissue thromboplastin that applies a varying frequency to detect blood coagulation at a lower frequency and at a higher frequency detects plasma coagulation factor concentration and/or activation, in combination with all other limitations in the claim.

The prior art of record fails to anticipate or make obvious the invention of claim 47, including, *inter-alia*, a blood analysis device comprising a transducer element, a biologically active substance in communication with the transducer, a bulk bioactive material for facilitating determination of a blood characteristic, a signal driver applying a varying signal to the transducer, an inlet port configured to direct blood to the transducer, and a signal processor that measures the blood's response to the applied signal and uses the response to determine a characteristic of the blood, in combination with all other limitations in the claim.

Response to Arguments

7. Applicant's amendments to claim 33 were sufficient to overcome the rejections under 35 USC 112 and 101 presented in the Office Action mailed 28 May 2009.

8. Applicant's other arguments with respect to claims 33-51 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735